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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,337	12/07/2001	Patrick Benoit	08888.0530	9440

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EXAMINER
GIBBS, TERRA C

ART UNIT	PAPER NUMBER
1635	8

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/005,337	BENOIT ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-39 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39, drawn to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, an expression cassette comprising a sequence encoding a protein or an RNA linked to said polynucleotide, and a vector comprising said expression cassette, classifiable in class 536, subclass 24.5.

II. Claims 1-39, drawn to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, an expression cassette comprising a sequence encoding a protein or an RNA linked to said polynucleotide, and a vector comprising said expression cassette, classifiable in class 536, subclass 24.5.

III. Claims 34 and 35, drawn to a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, classifiable in class 800, subclass 3.

IV. Claims 34 and 35, drawn to a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide comprising a fragment of SEQ ID NO:2, or a

fragment of a sequence that hybridizes with SEQ ID NO:2, classifiable in class 800, subclass 3.

V. Claims 37 and 38, drawn to a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, classifiable in class 514, subclass 44.

VI. Claims 37 and 38, drawn to a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, classifiable in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and II are related to the inventions of Groups V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in materially different processes of use. For example, the polynucleotides of Groups I and II can be used as hybridization probes in a method to identify gene expression, which is a materially

different process than a method for expressing a protein or an RNA in cells *in vivo* as in Groups V and VI.

The polynucleotides of Groups I and II are related to the transgenic nonhuman animal comprising a reporter gene linked to said polynucleotides of Groups III and IV by virtue of encoding same. Although the polynucleotide and transgenic nonhuman animal comprising a reporter gene linked to said polynucleotide are related because the transgenic nonhuman animal comprises a reporter gene linked to said polynucleotide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polynucleotide product can be used by another and materially different process other than the production of the transgenic nonhuman animal comprising said polynucleotide, such as a hybridization probe to identify gene expression.

Although the compositions of Groups I and II are related because they are drawn to a polynucleotide, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related compositions, restriction is deemed to be proper because these compositions constitute patentably distinct inventions for the following reasons: Group I employs SEQ ID NO:1 which would include different a molecule with a different chemical and physical structure not included in Group II (SEQ ID NO:2) so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1 of Group I would not encompass all of the art relevant to the

polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2 of Group II. Thus, they are patentably distinct from each other.

Although the transgenic nonhuman animal of Groups III and IV are related because they are drawn to a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related compositions, restriction is deemed to be proper because these compositions constitute patentably distinct inventions for the following reasons: Group III employs a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide of SEQ ID NO:1 which would include different a molecule with a different chemical and physical structure not included in Group IV, a transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide of SEQ ID NO:2, so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide of SEQ ID NO:1 of Group III would not encompass all of the art relevant to the transgenic nonhuman animal comprising a reporter gene linked to a polynucleotide of SEQ ID NO:2 of Group IV. Thus, they are patentably distinct from each other.

Although the methods of Groups V and VI are related because they are drawn to a method for expressing a protein or an RNA in cells *in vivo*, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following

reasons: Group V employs a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO:1, which would include different a molecule with a different chemical and physical structure not included in Group VI, a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2, so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:1, or a fragment of a sequence that hybridizes with SEQ ID NO1: of Group V would not encompass all of the art relevant to the a method for expressing a protein or an RNA in cells *in vivo*, comprising administering an expression cassette comprising a sequence encoding a protein or an RNA linked to a polynucleotide comprising a fragment of SEQ ID NO:2, or a fragment of a sequence that hybridizes with SEQ ID NO:2 of Group VI. The Inventions of Groups V and VI are materially distinct methods which differ in reagents and/or dosages, and criteria for success. Thus, they are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate

status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
September 11, 2003

Karen A. Lacourciere

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER